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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/497,943	02/04/2000	Mark Aaron Behlke	7614-018-999	8098

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EXAMINER

SISSON, BRADLEY L

ART UNIT	PAPER NUMBER
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1634

DATE MAILED: 04/23/2002

17

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/497,943

Applicant(s)

BEHLKE ET AL.

Examiner

Bradley L. Sisson

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 18 January 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 29-54 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 29-38 and 40-54 is/are rejected.
- 7) ☒ Claim(s) 39 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

Location of Application

1. The location of the subject application has changed. The subject application is now located in Group 1630, Art Unit 1634.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. Claims 51-54 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. As presently worded, the invention of claims 51-54 is that of a kit which comprises various nucleic acid sequences. The claims do not define them in terms of what they are other than to indicate that they are comprised of a range of nucleotides. Upon further review of the disclosure, the specification has not been found to provide an adequate written description of the genus of nucleic acids that are now claimed. Attention is directed to the decision in *Enzo Biochem Inc. v. Gen-Probe Inc.* (CAFC 01-1230, April 2002). There it was held that to define a nucleic acid in terms of it comprising nucleotides, or that it hybridizes to certain targets does not satisfy the written description requirement. As was the case in *Enzo*,

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applicant is claiming a broad genus of nucleic acid compounds, in short everything that would work, yet does not describe what they are.

4. In addition to the specification failing to provide an adequate written description of the genus of nucleic acids encompassed by the kit claims, the specification also does not satisfy the possession test either. *Enzo*. It is well settled that the specification, along with enabling the use of a product and providing an adequate written description of the claimed invention, must also reasonably suggest that applicant was in possession of the invention at the time of filing. A review of the disclosure does not find a showing of where applicant was in possession of the myriad nucleic acid sequences. See *Lockwood v. American Airlines, Inc.* (Fed. Cir. 1997) 41 USPQ2d 1961, 1966.

Claim Rejections - 35 USC § 102

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

6. The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) do not apply to the examination of this application as the application being examined was not (1) filed on or after November 29, 2000, or (2) voluntarily published under 35 U.S.C. 122(b). Therefore, this application is examined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

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7. Claims 29, 30, 32, 33, 40, and 44 remain rejected under 35 U.S.C. 102(e) as being anticipated by Shuber.

8. Shuber, column 2, third paragraph, and column 4, third paragraph, discloses the use of a chimeric primer that is described as being configured 5'-XY-3'. The "X" domain "comprises a sequence that does not hybridize to the target sequence." The "Y" domain "comprises a sequence contained within or flanking the target sequence or its complement." Accordingly, the "X" domain meets the limitations of applicants "Signal Template Domain" and the "Y" domain meets the limitations of the "Substrate hybridization Domain" of the "first sequence." The target sequence meets the limitations of applicant's second sequence. As seen at column 4, the respective domains may be comprised of nearly any nucleotide sequence and that it can range in length from 17 to 25 bases. Such a limitation is considered to meet the limitation of claim 34 where the Substrate Hybridization Domain "comprises a sequence of about 5 to 10 nucleotides" (emphasis added).

Response to arguments

9. At page 6 of the response received 18 January 2002, hereinafter the response, it is asserted that the patent of Shuber does not meet the limitations of the claimed invention as it is asserted that the first strand of the claimed method is to serve as a template, not a primer, and that Shuber's target does not meet the limitation of applicant's second sequence. This argument has been fully considered and has not been found persuasive. It is noted with particularity that neither of applicant's sequences are defined in terms of primer or template, but rather, they are defined as having a sequence length of about 105 to about 120 nucleotides (applicant's first sequence) and about 5 to 20 nucleotides (applicant's second sequence). It is further noted that

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the claim's leave open the inclusion of additional nucleotides, for both sequences. Upon review of claim 29, the first independent claim, it is noted that there is a protruding end for both the first and second sequences and that both sequences would strand to be extended. In such a scenario, both strands could serve as both primer and template. Accordingly, applicant's argument is not found persuasive as applicant "Substrate Hybridization Domain" which is considered capable of being extended over any protruding portion of the second sequence, is fairly taught by Shuber where their "3' 'half'" comprises a target-specific sequence." Regardless of names applied, both methods utilize two nucleotide sequences that are partially complementary and which can both be extended by the use of a 5' to 3' polymerase. Accordingly, and in the absence of convincing evidence to the contrary, the rejection is maintained.

Claim Rejections - 35 USC § 103

10. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

11. Claim 31 is rejected under 35 U.S.C. 103(a) as being unpatentable over Shuber in view of Khan et al

12. See above for the basis of the rejection as it relates to the teachings of Shuber.

13. Khan et al., column 8, disclose that suitable templates include DNA as well as RNA.

14. It would have been obvious to one of ordinary skill in the art to have modified the method of Shuber whereby RNA was used as a template and to have used a RNA dependent

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DNA polymerase so as to generate cDNA runoffs as such would be more resistant to degradation and thereby provide the artisan with a more stable resource for further investigation.

15. In view of the well-developed nature of the art, the skilled artisan would have had a reasonable expectation of success.

16. Claims 35-38, 41-43 and 48 are rejected under 35 U.S.C. 103(a) as being unpatentable over Shuber in view of Grossman et al. and Khan et al.

17. See above for the basis of the rejection as it relates to the disclosure of Shuber.

18. Shuber does not disclose the use of homopolymeric tails.

19. Grossman et al., column 19, discloses the generation of homopolymeric tails. Also disclosed is the use of a detectable nucleotide, e.g., a fluorophore (applicant's fluorescein).

20. Khan et al., column 5, sixth paragraph, disclose a plethora of labels that can be used in primer extension reactions. As seen therein, such labels include fluorophores, radioisotopes, biotin, etc.

21. Khan et al., column 5, disclose the use of modified nucleotides, e.g., dideoxynucleotides, which proscribe primer elongation.

22. It would have been obvious to one of ordinary skill in the art at the time the invention was made to have incorporated any one of the labels disclosed by Khan et al., and Grossman et al., into either strand, or the nucleotides to be incorporated into the prime extension product of Shuber as such would have accorded the ordinary artisan with a easy means for identifying the product of any reaction as well as individual reagents.

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23. It would have also been obvious to have incorporated the use of a chain terminating nucleotide into a specific sequence so to limit the amount and direction of any extension reaction. Given the well-developed use of chain terminating nucleotides, the ordinary skilled artisan would have had a reasonable expectation of success.

24. Claim 45-47 is rejected under 35 U.S.C. 103(a) as being unpatentable over Shuber in view of Brown.

25. See above for the basis of the rejection as it relates to the disclosure of Shuber.

26. Shuber does not disclose the use of 2, 6-diaminopurine.

27. Brown et al., discloses the use of 2, 6-diaminopurine in oligonucleotides and their use in primer extension reactions.

28. It would have been obvious to one of ordinary skill in the art to have incorporated the use of 2, 6-diaminopurine into the sequences utilized by Shuber for the obvious improvements as disclosed by Brown.

Response to arguments

29. Applicant presents arguments that the rejections of claims wherein Shuber was used as a prior-art reference must fall as they contend that Shuber fails to teach the claimed invention. As shown above, this argument has not been found persuasive and the rejection of claims under 35 USC 102 and under 35 USC 103(a) have been maintained.

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Allowable Subject Matter

30. Claim 39 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Conclusion

31. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bradley L. Sisson whose telephone number is (703) 308-3978. The examiner can normally be reached on 6:30 a.m. to 5 p.m., Monday through Thursday.

32. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, W. Gary Jones can be reached on (703) 308-1152. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 872-9306 for regular communications and (703) 872-9307 for After Final communications.

33. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.



Bradley L. Sisson
Primary Examiner
Art Unit 1634

BLS
April 19, 2002